RVD2008-15

Re-evaluation Decision

Pyrazon

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

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Table of Contents

Overview 1
- Re-evaluation Decision 1
- What Does Health Canada Consider When Making a Re-evaluation Decision? 2
- What Is Pyrazon? 2
- Health Considerations 3
- Environmental Considerations 4
- Measures to Minimize Risk 4
- Other Information 5

Appendix I Comments and Responses 7

Appendix II Label Amendments for Products Containing Pyrazon 9

Appendix III Revised Inputs to Buffer Zone Models for Pyrazon 13

Overview

Re-evaluation Decision

After a re-evaluation of the herbicide pyrazon, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing pyrazon.

An evaluation of available scientific information found that products containing pyrazon do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of pyrazon uses, new risk-reduction measures must be included on the labels of products containing pyrazon.

The regulatory approach for the re-evaluation of pyrazon was first presented in Proposed Re-evaluation Document PRVD2007-15, *Pyrazon*, a consultation document.[1] This Re-evaluation Decision Document[2] describes this stage of PMRA's regulatory process for the re-evaluation of pyrazon as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-15. To comply with this decision, registrants of products containing pyrazon will be informed of the specific requirements affecting their product registration(s) and of regulatory options available to them.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Pyrazon, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA is taking a regulatory decision and is requiring appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated pyrazon and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation section of the related Proposed Re-evaluation Decision PRVD2007-15, *Pyrazon*.

What Is Pyrazon?

Pyrazon is a herbicide used to control annual broadleaved weeds in sugar beets and red table beets. Pyrazon is applied by farm workers and professional applicators using ground equipment.

Health Considerations

Can Approved Uses of Pyrazon Affect Human Health?

Pyrazon is unlikely to affect your health when used according to the revised label directions.

People could be exposed to pyrazon through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that pyrazon was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Pyrazon is currently registered in Canada for use on red table beets and sugar beets and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for pyrazon in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Pyrazon Is Introduced Into the Environment?

Pyrazon is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to pyrazon in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that reregistration of pyrazon was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required. Furthermore, the PMRA will require terrestrial and aquatic buffer zones for pyrazon end-use products to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of pyrazon, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- A restricted-entry interval to protect workers re-entering treated sites

Environment

- Additional advisory label statements to reduce potential spray drift and runoff
- Buffer zones to protect sensitive aquatic and terrestrial habitats

Appendix II lists all required label amendments.

Other Information

Any person may file a notice of objection[3] regarding this decision on pyrazon within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on Size of Terrestrial Buffer Zone

The proposed buffer zone of 5 m from sensitive habitat will be a challenge for red table beet and sugar beet growers. Large untreated areas of fields could act as a weed bank. This could increase problems with weed management in the remainder of the field.

If buffer zones are required for windbreaks, this would contradict the use of windbreaks and could discourage new plantings of windbreaks.

The inclusion of air induction technology on pesticide labels would provide another option for growers to reduce spray drift, and consequently reduce buffer zone requirements.

Response

The proposed buffer zone distance of 5 m in PRVD2007-15 is based on calculations that are risk-based (the greater the risk, the larger the buffer zone). Buffer zone calculations were carried out using the maximum application rate for sugar beet from the Canadian labels and toxicity data from the USEPA Reregistration Eligibility Decision on pyrazon. It is understood, however, that the use patterns of the herbicide pyrazon with regard to red table beet and sugar beet can involve band application and that the application rate also varies by soil type (light, medium or heavy soil).

With band treatment, the spray nozzles are closer to the ground than for broadcast ground application so as to obtain the narrow strips of treated soil. With the nozzle-to-ground distance being less than in broadcast ground applications, spray drift is expected to be less and hence the buffer zones would be reduced. As a result, the buffer zones have been recalculated based on soil type (light, medium, heavy) and taking into account whether broadcast or band application is used, incorporating a spray drift reduction factor to compensate for the lower boom height when using band application. The calculations were further revised to reflect current methods. The revised buffer zone label amendments are listed in Appendix II and revised buffer zone input values are presented in Appendix III.

It should be recognized that buffer zones are required only if sensitive habitats are downwind from the point of application. Buffer zones are not required when sensitive habitats are upwind from the application area and, if necessary, a previously unsprayed area could be sprayed at another time under favourable meteorological conditions.

With regard to the issue of potential weed banks in untreated areas, the PMRA did approach the provinces concerning collaboration on the implementation of buffer zones with provincial noxious weed regulations; however, the issue is currently unresolved. The issue will be addressed at a future workshop being planned by PMRA in 2008 on defining terrestrial habitats.

Windbreaks are considered part of sensitive terrestrial habitat. The PMRA is aware of the issues concerning windbreaks and is in the process of developing a solution. The PMRA is currently examining terrestrial habitats and what types should be included or excluded from the buffer zone requirement. The PMRA is planning a workshop in 2008 to examine this issue. As indicated previously, if there is no wind blowing towards the windbreak, a buffer zone is not required.

The PMRA recognizes that recent improvements in nozzle technology have resulted in a number of low drift nozzles, such as air induction nozzles, being released on the market and that these nozzles are being used in the field. Unfortunately, the PMRA has not yet been able to review drift reduction data for these air induction nozzles; therefore, we are not able to provide buffer zone reductions for their use at this time.

Appendix II Label Amendments for Products Containing Pyrazon

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

> Do not enter or allow worker entry into treated areas for 12 hours following application.

II) The following statements must be included in the **DIRECTIONS FOR USE** section:

> Field sprayer application: DO NOT apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) fine/medium/coarse classification. Boom height must be 60 cm or less above the crop or ground.
>
> DO NOT apply by air.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths		Estuarine/Marine Habitats of Depths		Terrestrial Habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Sugar beets, red table beets (broadcast application to heavy or medium soils)	1	1	1	1	5
	Sugar beets, red table beets (broadcast application to light soils or postemergence broadcast application to all soils)	1	1	1	1	4
	Sugar beets, red table beets (band application)	1	1	1	1	3

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

III) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

TOXIC to aquatic organisms and terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats. DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Appendix III Revised Inputs to Buffer Zone Models for Pyrazon

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Applications**	**Maximum Application Rate (g a.i./ha)**
Sugar beets, red table beets (broadcast application to heavy or medium soils)	Suspension or dry flowable	Field sprayer (broadcast)	1	4400
Sugar beets, red table beets (broadcast application to light soils or postemergence broadcast application to all soils)	Suspension or dry flowable	Field sprayer (broadcast)	1	3600
Sugar beets, red table beets (band application)	Suspension or dry flowable	Field sprayer (banded)	1	2800

Model Input Data for Aquatic Buffer Zones (from 2005 RED)		
Half-life for aquatic buffer zones	Assumed stable	
Most sensitive amphibian species	Rainbow trout (surrogate)	1/10 LC_{50} = 3.2 mg a.i./L
Most sensitive freshwater species	*Selenastrum capricornutum*	½ EC_{50} = 0.085 mg a.i./L
Most sensitive estuarine/marine species	*Selenastrum capricornutum*	½ EC_{50} = 0.085 mg a.i./L

Model Input Data for Terrestrial Buffer Zones (from 2005 RED)		
Half-life for terrestrial buffer zones	Assumed stable	
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	Cucumber (vegetative vigour)	EC_{25} = 37.1 g a.i./ha